

PATENT

Attorney Docket No. **FORS-06638**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: *J. Prudent et al.*

Serial No.: 09/982,667

Group No.: 1637

Filed: 10/18/01

Examiner: Jezia Riley

Entitled: **INVASIVE CLEAVAGE OF NUCLEIC ACIDS**

**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date:

1/29/05

By:

David Casimir

Sir or Madam:

The patents and applications listed below may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The following is a listing of these co-owned patents and applications, along with any substantive office actions received (identified by mailing dates). Restriction requirements, notices of missing parts and communications relating to formalities are omitted. Copies of all the office actions listed below (with cited art omitted) are included herewith. The Examiner is requested to make these patents, applications and the associated office actions of official record in this application.

- **Application Serial No.: 08/599,491**
 - o Office Communication mailed: 10/18/96
 - o Office Communication mailed: 08/11/97

- **Application Serial No.: 08/682,853**
 - o Office Communication mailed: 10/29/97
 - o Office Communication mailed: 04/23/98
 - o Office Communication mailed: 09/18/98
 - o Office Communication mailed: 12/17/98
 - o Office Communication mailed: 03/23/99
- **Application Serial No.: 08/756,386**
 - o Office Communication mailed: 09/02/98
- **Application Serial No.: 08/759,038**
 - o Office Communication mailed: 09/19/97
 - o Office Communication mailed: 03/12/98
- **Application Serial No.: 08/823,516**
 - o Office Communication mailed: 01/26/98
- **Application Serial No.: 09/308,825**
 - o Office Communication mailed: 05/09/00
 - o Office Communication mailed: 09/20/00
 - o Office Communication mailed: 03/22/01
- **Application Serial No.: 09/350,309**
 - o Office Communication mailed: 11/22/00
- **Application Serial No.: 09/350,597**
 - o Office Communication mailed: 10/03/00
 - o Office Communication mailed: 08/28/01
- **Application Serial No.: 09/381,212**
 - o Office Communication mailed: 10/25/00
 - o Office Communication mailed: 09/26/01
 - o Office Communication mailed: 04/09/02
 - o Office Communication mailed: 07/16/02
 - o Office Communication mailed: 12/03/02
 - o Office Communication mailed: 12/08/04
- **Application Serial No.: 09/940,925**
 - o Office Communication mailed: 12/24/02
 - o Office Communication mailed: 06/17/03
 - o Office Communication mailed: 01/16/04
 - o Office Communication mailed: 03/31/04
 - o Office Communication mailed: 08/09/04
 - o Office Communication mailed: 10/28/04

- **Application Serial No.: 09/941,193**
 - o Office Communication mailed: 04/20/04
- **Application Serial No.: 09/655,378**
 - o Office Communication mailed: 08/15/01
 - o Office Communication mailed: 04/23/02
 - o Office Communication mailed: 08/13/02
 - o Office Communication mailed: 04/24/03
 - o Office Communication mailed: 12/07/04
- **Application Serial No.: 09/660,924**
 - o Office Communication mailed: 07/17/01
 - o Office Communication mailed: 11/02/01
 - o Office Communication mailed: 07/29/02
 - o Office Communication mailed: 05/21/03
 - o Office Communication mailed: 04/07/04
- **Application Serial No.: 09/940,244**
 - o Office Communication mailed: 04/10/03
- **Application Serial No.: 10/081,806 (6910)**
 - o Office Communication mailed: 12/31/02
 - o Office Communication mailed: 11/26/03
- **Application Serial No.: 09/713,601**
 - o Office Communication mailed: 08/15/02
 - o Office Communication mailed: 05/23/03
 - o Office Communication mailed: 12/03/03
- **Application Serial No.: 10/033,297**
 - o Office Communication mailed: 01/05/04
 - o Office Communication mailed: 04/20/04
 - o Office Communication mailed: 01/11/05

The following applications have not received any substantive office communication to date:

- **Application Serial No.: 09/732,622**
- **Application Serial No.: 10/309,584**
- **Application Serial No.: 10/897,793**

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these

citations of official record in this application.

- Hessner *et al.*, Genotyping of Factor V G1691A (Leiden) without the Use of PCR by Invasive Cleavage of Oligonucleotide Probes, *Clinical Chemistry* 46:1051-1056 (2000)
- Lyamichev *et al.*, Experimental and Theoretical Analysis of the Invasive Signal Amplification Reaction, *Biochemistry* 39:9523-9532 (2000)
- Neri *et al.*, Transferring Automation for Large-scale Development and Production of Invader™ SNP Assays, *Progress in Biomedical Optics* 1:117-125 (2000)
- Newlin *et al.*, The Invader Assay: An Alternative To PCR-Based Testing For The Detection Of Point Mutations Associated With Venous Thrombosis, *Clinical Hemostasis Review*, 14:10-12 (2000)
- Hall *et al.*, Sensitive detection of DNA polymorphisms by the serial invasive signal amplification reaction, *PNAS* 97:8272-8277 (2000)
- Ledford *et al.*, A Multi-Site Study for Detection of the Factor V (Leiden) Mutation from Genomic DNA Using a Homogeneous Invader Microtiter Plate Fluorescence Resonance Energy Transfer (FRET) Assay, *J. Molecular Diagnostics* 2:97-104 (2000)
- Ma *et al.*, RNA Template-dependent 5' Nuclease Activity of *Thermus aquaticus* and *Thermus thermophilus* DNA Polymerases, *J. Biol.Chem.*, 275:24693-24700 (2000)
- Fors *et al.*, Large-scale SNP scoring from unamplified genomic DNA, *Pharmacogenomics* 1(2):219-229 (2000)
- Agarwal *et al.*, Comparison Study For Identifying Promoter Allelic Polymorphism in Interleukin 10 and Tumor Necrosis Factor α Genes, *Diagn Mol Pathol* 9(3):158-164 (2000)
- Cooksey *et al.*, Evaluation of the Invader Assay, a Linear Signal Amplification Method, for Identification of Mutations Associated with Resistance to Rifampin and Isoniazid in *Mycobacterium tuberculosis*, *Antimicrobial Agents and Chemotherapy*, 44:1296-1301 (2000)
- Mein *et al.*, Evaluation of Single Nucleotide Polymorphism Typing with Invader or PCR Amplicons and Its Automation, *Genome Research* 10:330-343 (2000)

- Lieder, Excitement Builds in Molecular Biology, *Advance for Administrators of the Laboratory* 50-52 (1999)
- Lieder, Invader Technology Provides Alternative to PCR, *Advance for Administrators of the Laboratory*, 70-71 (2000)
- Treble *et al.*, Invader ® technology for SNP detection, *Gene & Medicine* 4:68-72 (2000)
- Kwiatkowski *et al.*, Clinical, Genetic, and Pharmacogenetic Applications of the Invader Assay, *Molecular Diagnosis*, 4:353-364 (1999)
- Check, Labs home in on mutant alleles, *College of American Pathologists Today*, 1-5 September (1999)
- Griffin *et al.*, Direct genetic analysis by matrix-assisted laser desorption/ionization mass spectrometry, *PNAS* 96:6301-6306 (1999)
- Ryan *et al.*, Non-PCR-Dependent Detection of the Factor V Leiden Mutation From Genomic DNA Using a Homogeneous Invader Microtiter Plate Assay, *Molecular Diagnosis*, 4:135-144 (1999)
- Kaiser *et al.*, A Comparison of Eubacterial and Archaeal Structure-specific 5'-Exonucleases, *J. Biol. Chem.*, 274:21387-21394 (1999)
- Lyamichev *et al.*, Polymorphism identification and quantitative detection of genomic DNA by invasive cleavage of oligonucleotide probes, *Nature Biotech.* 17:292-296-(1999)
- Harrington, The Characterization of the Fen-1 Family of Structure-Specific Endonucleases: Implications For DNA Replication, Recombination, And Repair, Dissertation submitted to the Program in Cancer Biology and the Committee on Graduate Studies of Stanford University (1994)
- DeFrancesco, The Next New Wave in Genome Analysis, *The Scientist*, 12(21):1-3 (1998)

The present application is a continuation of U.S. Patent No. 6,348,314 and is related to U.S. Patent No. 6,090,543. These patents have been the subject of litigation in two separate patent infringement suits: *Third Wave Technologies, Inc. v. EraGen Biosciences, Inc.*, Civil Case No. 3:2002cv00507 (W.D. Wis.) (the "*Third Wave v. EraGen*" litigation), and *Third Wave*

Technologies, Inc. v. Stratagene Corporation, Civil Case No. 3:2004cv00680 (W.D. Wis.)(the "*Third Wave v. Stratagene*" litigation).

The following documents relate to the *Third Wave v. EraGen* litigation:

- Docket Sheet for Civil Case No. 3:2002cv00507-C (W.D. Wis), filed 09/06/2002, closed on 04/14/2003;
- Complaint, filed 09/06/2002;
- Answer, Affirmative Defenses and Counterclaim, filed 10/07/2002;
- Third Wave Technologies' Reply to Defendant Eragen's Counterclaim, October 28, 2002
- Third Wave Technologies' Motion to Strike Eragen's Affirmative Defenses and Counterclaim of Invalidity, October 28, 2002;
- Defendant's Brief in Opposition to Plaintiff's Motion to Strike Eragen's Affirmative Defenses and Counterclaim of Invalidity, November 15, 2002;
- Third Wave Technologies' Reply in Support of Its Motion to Strike Eragen's Affirmative Defenses and Counterclaim of Invalidity, November 25, 2002;
- Defendant's Surreply in Opposition to Plaintiff's Motion to Strike Eragen's Affirmative Defenses and Counterclaim of Invalidity, November 27, 2002;
- Plaintiff's Response to Defendant's First Set of Interrogatories to Third Wave Technologies, Inc., November 21, 2002;
- Plaintiff's Amended Response to Defendant's First Set of Interrogatories to Third Wave Technologies, Inc., November 21, 2002December 3, 2002;
- Defendant's Rule 26(a)(1) Disclosures; November 4, 2002;
- Defendant's Responses to TWT's Expedited Third Set of Interrogatories (Nos. 15-16), January 27, 2003;
- Defendant's Amended Responses to TWT's Expedited Third Set of Interrogatories (Nos. 15-16), March 28, 2003;
- Order on Claims Construction Hearing, March 19, 2003.

If the Examiner would consider any additional pleadings or documents to be helpful or pertinent, Applicants would be pleased to provide them (to the extent possible given Protective

Order constraints).

During the course of the *Third Wave v. EraGen* litigation, EraGen stated an intention to assert that the work reported in the following publication was performed prior to the filing of date of U.S. Patent No. 5,846,717, to which both the '543 and '314 patents claim priority:

- Lyamichev, *et al.*, Comparison of the 5' nuclease activities of Taq DNA polymerase and its isolated nuclease domain. *Proc Natl Acad Sci U S A* 96: 6143-6148 (1999)

The following documents relate to the *Third Wave v. Stratagene* litigation, described above.

- Docket Sheet for Civil Case No. 04-C-0680-C (W.D.Wis), filed 09/15/2004;
- Complaint, 09/15/2004;
- Answer, 10/20/2004;
- Amended Answer and Counterclaims, December 30, 2004.

In the *Third Wave v. Stratagene* litigation, Stratagene has asserted that the following new reference may be relevant to the case (copy attached).

- Turchi, *et al.*, Completion of Mammalian Lagging Strand DNA Replication Using Purified Proteins. *J. Biol Chem.* 268(20):15136-141 (1993)

If the Examiner would consider any additional pleadings or documents to be helpful or pertinent, Applicants would be pleased to provide them (to the extent possible given Protective Order constraints). Stratagene was asked for permission to submit, in this IDS, confidential/restricted documents and information that Stratagene has provided to Third Wave's litigation counsel during the course of the *Third Wave v. Stratagene* litigation (*e.g.*, responses to interrogatories). Stratagene has denied permission. If the Examiner would like to see any such information, please let us know and we will seek a Court order compelling Stratagene to allow Third Wave to provide this confidential information.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to

the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: January 29, 2005



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San Francisco, California 94105

FORM PTO-1449
(Modified)

U.S. Department of Commerce
Patent and Trademark Office

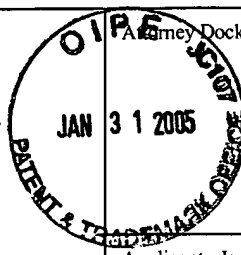
~~P.F.~~ Attorney Docket No.: FORS-06638

Serial No.: 09/982,667

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use Several Sheets If Necessary)

(37 CFR ? 1.98(b))



Applicant: James R. PRUDENT *et al.*

Filing Date: 10/18/01

Group Art Unit:

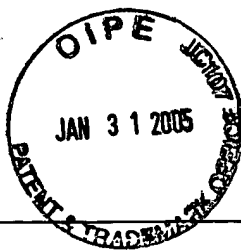
U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	6,348,314					
	2	6,090,543					
	3	5,846,717					
	4	08/599,491					
	5	08/682,853					
	6	08/756,386					
	7	08/759,038					
	8	08/823,516					
	9	09/308,825					
	10	09/350,309					
	11	09/350,597					
	12	09/381,212					
	13	09/940,925					
	14	09/941,193					
	15	09/655,378					
	16	09/660,924					
	17	09/940,244					
	18	10/081,806					
	19	09/713,601					
	20	10/033,297					
	21	09/732,622					
	22	10/309,584					
	23	10/891,793					

Examiner:

Date Considered:

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449 U.S. Department of Commerce (Modified) Patent and Trademark Office		Attorney Docket No.: FORS-06638	Serial No.: 09/982,667
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR ? 1.98(b))		Applicant: James R. PRUDENT <i>et al.</i>	
		Filing Date: 10/18/01	Group Art Unit:
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)			
24	Hessner <i>et al.</i> , Genotyping of Factor V G1691A (Leiden) without the Use of PCR by Invasive Cleavage of Oligonucleotide Probes, <i>Clinical Chemistry</i> 46:1051-1056 (2000)		
25	Lyamichev <i>et al.</i> , Experimental and Theoretical Analysis of the Invasive Signal Amplification Reaction, <i>Biochemistry</i> 39:9523-9532 (2000)		
26	Neri <i>et al.</i> , Transferring Automation for Large-scale Development and Production of Invader™ SNP Assays, <i>Progress in Biomedical Optics</i> 1:117-125 (2000)		
27	Newlin <i>et al.</i> , The Invader Assay: An Alternative To PCR-Based Testing For The Detection Of Point Mutations Associated With Venous Thrombosis, <i>Clinical Hemostasis Review</i> , 14:10-12 (2000)		
28	Hall <i>et al.</i> , Sensitive detection of DNA polymorphisms by the serial invasive signal amplification reaction, <i>PNAS</i> 97:8272-8277 (2000)		
29	Ledford <i>et al.</i> , A Multi-Site Study for Detection of the Factor V (Leiden) Mutation from Genomic DNA Using a Homogeneous Invader Microtiter Plate Fluorescence Resonance Energy Transfer (FRET) Assay, <i>J. Molecular Diagnostics</i> 2:97-104 (2000)		
30	Ma <i>et al.</i> , RNA Template-dependent 5' Nuclease Activity of <i>Thermus aquaticus</i> and <i>Thermus thermophilus</i> DNA Polymerases, <i>J. Biol. Chem.</i> , 275:24693-24700 (2000)		
31	Fors <i>et al.</i> , Large-scale SNP scoring from unamplified genomic DNA, <i>Pharmacogenomics</i> 1(2):219-229 (2000)		
32	Agarwal <i>et al.</i> , Comparison Study For Identifying Promoter Allelic Polymorphism in Interleukin 10 and Tumor Necrosis Factor α Genes, <i>Diagn Mol Pathol</i> 9(3):158-164 (2000)		
33	Cooksey <i>et al.</i> , Evaluation of the Invader Assay, a Linear Signal Amplification Method, for Identification of Mutations Associated with Resistance to Rifampin and Isoniazid in <i>Mycobacterium tuberculosis</i> , <i>Antimicrobial Agents and Chemotherapy</i> , 44:1296-1301 (2000)		
34	Mein <i>et al.</i> , Evaluation of Single Nucleotide Polymorphism Typing with Invader or PCR Amplicons and Its Automation, <i>Genome Research</i> 10:330-343 (2000)		
35	Lieder, Excitement Builds in Molecular Biology, <i>Advance for Administrators of the Laboratory</i> 50-52 (1999)		
36	Lieder, Invader Technology Provides Alternative to PCR, <i>Advance for Administrators of the Laboratory</i> , 70-71 (2000)		
37	Treble <i>et al.</i> , Invader ? technology for SNP detection, <i>Gene & Medicine</i> 4:68-72 (2000)		
38	Kwiatkowski <i>et al.</i> , Clinical, Genetic, and Pharmacogenetic Applications of the Invader Assay, <i>Molecular Diagnosis</i> , 4:353-364 (1999)		
39	Check, Labs home in on mutant alleles, <i>College of American Pathologists Today</i> , 1-5 September (1999)		
40	Griffin <i>et al.</i> , Direct genetic analysis by matrix-assisted laser desorption/ionization mass spectrometry, <i>PNAS</i> 96:6301-6306 (1999)		
41	Ryan <i>et al.</i> , Non-PCR-Dependent Detection of the Factor V Leiden Mutation From Genomic DNA Using a Homogeneous Invader Microtiter Plate Assay, <i>Molecular Diagnosis</i> , 4:135-144 (1999)		
42	Kaiser <i>et al.</i> , A Comparison of Eubacterial and Archaeal Structure-specific 5'-Exonucleases, <i>J. Biol. Chem.</i> , 274:21387-21394 (1999)		
43	Lyamichev <i>et al.</i> , Polymorphism identification and quantitative detection of genomic DNA by invasive cleavage of oligonucleotide probes, <i>Nature Biotech.</i> 17:292-296-(1999)		
44	Harrington, The Characterization of the Fen-1 Family of Structure-Specific Endonucleases: Implications For DNA Replication, Recombination, And Repair, Dissertation submitted to the Program in Cancer Biology and the Committee on Graduate Studies of Stanford University (1994)		
45	DeFrancesco, The Next New Wave in Genome Analysis, <i>The Scientist</i> , 12(21):1-3 (1998)		
Examiner:		Date Considered:	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

FORM PTO-1449
(Modified)

Attorney Docket No.: FORS-06638

Serial No.: 09/982,667

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use Several Sheets If Necessary)

(37 CFR ? 1.98(b))

Applicant: James R. PRUDENT *et al.*

Filing Date: 10/18/01

Group Art Unit:

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

46	Lyamichev, <i>et al.</i> , Comparison of the 5' nuclease activities of Taq DNA polymerase and its isolated nuclease domain. <i>Proc Natl Acad Sci U S A</i> 96: 6143-6148 (1999)
47	Turchi, <i>et al.</i> , Completion of Mammalian Lagging Strand DNA Replication Using Purified Proteins. <i>J. Biol Chem.</i> 268(20):15136-141 (1993)
48	<i>Third Wave Technologies, Inc. v. EraGen Biosciences, Inc.</i> , Civil Case No. 3:2002cv00507 (W.D. Wis.) (the " <i>Third Wave v. EraGen</i> " litigation)
49	<i>Third Wave Technologies, Inc. v. Stratagene Corporation</i> , Civil Case No. 3:2004cv00680 (W.D. Wis.)(the " <i>Third Wave v. Stratagene</i> " litigation)
50	Docket Sheet for Civil Case No. 3:2002cv00507-C (W.D.Wis), filed 09/06/2002, closed on 04/14/2003
51	Complaint, filed 09/06/2002
52	Answer, Affirmative Defenses and Counterclaim, filed 10/07/2002
53	Third Wave Technologies' Reply to Defendant Eragen's Counterclaim, October 28, 2002
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55	Defendant's Brief in Opposition to Plaintiff's Motion to Strike Eragen's Affirmative Defenses and Counterclaim of Invalidity, November 15, 2002
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60	Defendant's Rule 26(a)(1) Disclosures; November 4, 2002
61	Defendant's Responses to TWT's Expedited Third Set of Interrogatories (Nos. 15-16), January 27, 2003
62	Defendant's Amended Responses to TWT's Expedited Third Set of Interrogatories (Nos. 15-16), March 28, 2003
63	Order on Claims Construction Hearing, March 19, 2003
64	Docket Sheet for Civil Case No. 04-C-0680-C (W.D.Wis), filed 09/15/2004
65	Complaint, 09/15/2004
66	Answer, 10/20/2004
67	Amended Answer and Counterclaims, December 30, 2004

Examiner:

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